IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 04-939 (JJF)
THE PROCTER & GAMBLE CO., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 04-940 (JJF)

DEFENDANT'S MEMORANDUM IN SUPPORT OF CONSOLIDATION

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INTRODUCTION

Teva Pharmaceuticals USA, Inc., defendant in both of the above-captioned cases, submits this memorandum in response to the Court's orders in those cases of March 3, 2005, requesting that Teva submit a "memo setting forth the advantages and disadvantages of consolidation." For the reasons set forth below, these two cases involve common issues of law and fact, and their consolidation would promote judicial efficiency and save the parties time and expense. Indeed, to maintain them separately, when they relate to the identical subject matter and are already on the same schedule, would be wasteful and inefficient. In short, consolidation presents nothing but advantages for the parties and the Court.

BACKGROUND

Both cases arise from the same act: Teva's submission of an Abbreviated New Drug Application and the accompanying "paragraph IV" patent certification. On July 2, 2004, defendant Teva gave notice to Procter & Gamble ("P&G") and to Merck & Co. ("Merck") of the filing of a paragraph IV certification in ANDA No. 77-132 , as required under 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii). This certification asserted that Teva's proposed formulation of its generic versions of the drug "Actonel," whose active ingredient is the chemical compound risedronate, would not infringe any of the patents listed in the FDA's "Orange Book" in connection with that drug, or that those patents are invalid or unenforceable.

Actonel is marketed by P&G, the plaintiff in Civil Action No. 04-940, for the treatment of osteoporosis and Paget's disease of bone. The patents listed in the Orange Book for Actonel include P&G's U.S. Patent 5,583,122, which claims risedronate as well

as its use in the treatment of osteoporosis. In addition to the '122 patent, the Orange Book also lists for Actonel three patents belonging to Merck, the plaintiff in Civil Action No. 04-939: U.S. Patents 5,994,329, 6,432,932, and 6,465,443. These patents include claims for once-weekly administration of risedronate for the treatment of osteoporosis and "kits" for such administration. The Merck patents are listed in connection with P&G's drug because Merck has licensed P&G under those patents.

On Aug. 13, 2004, P&G filed suit against Teva in this Court for infringement of the '122 patent under 35 U.S.C. § 271(e)(2)(A), alleging as an act of infringement Teva's filing of its ANDA for risedronate. That same day, Merck also sued Teva in this Court, alleging that the same act was also an infringement of its three "Orange Book" patents. Teva filed answers to both complaints on Oct. 4, 2004. On February 8, 2005, the parties in both cases submitted proposed scheduling orders. (D.I. 8 in No. 939 and D.I. 10 in No. 940). Both proposals include the same dates for all deadlines before the final pretrial conference, including completion of fact discovery, exchange of expert reports, and submission of *Markman* briefs.

THE TWO CASES SHOULD BE CONSOLIDATED

The Court has broad powers under Fed. R. Civ. P. 42(a) to consolidate actions involving common questions of law or fact, if "in its discretion, such consolidation would facilitate the administration of justice." *Waste Distillation Tech., Inc. v. Pan Am. Res., Inc.*, 775 F. Supp. 759, 761 (D. Del. 1991) (citations omitted); *Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1309-10 (D. Del. 1981). "[R]elevant considerations, such as commonality of factual and legal issues, identity of parties, and overlap in discovery, typically dictate consolidation." *United States v. Dentsply Int'l, Inc.*, 190 F.R.D. 140, 141 (D. Del. 1999). In view of the obvious administrative benefits that flow

from consolidating multiple cases on a court's calendar, the principles of judicial economy generally favor consolidation. *See, e.g., Ellerman Lines, Ltd. v. Atlantic & Gulf Stevedores, Inc.*, 339 F.2d 673, 675 (3d Cir. 1964); *Waste Distillation Tech., Inc.*, 775 F. Supp. at 761.

When considering consolidation, a court must balance the savings of time and effort gained by consolidation against the inconvenience, delay, or expense that might result from simultaneous disposition of separate actions. *Waste Distillation Tech.*, 775 F. Supp. at 675. If the court finds that the disadvantages do not outweigh the advantages of consolidation, the proper administration of justice requires consolidation. *See Ellerman Lines, Ltd.*, 339 F.2d at 675.

I. COMMON QUESTIONS OF LAW AND FACT FAVOR CONSOLIDATION

The central issue in both the *P&G* and the *Merck* litigations is identical – whether Teva's marketing of its generic formulation of risedronate would infringe patents claiming risedronate or its use. In both cases, the ANDA is the same – Teva's ANDA for risedronate. In both cases, the products are the same: P&G's Actonel and Teva's proposed generic equivalent. In both cases the patents claim risedronate or its use. P&G has a legal interest in all the patents in both cases. In both cases, a central issue is the validity of those patents. In both cases, Teva alleges the same affirmative defense: that the patents in suit are invalid. In both cases, the requested relief is the same: an injunction against Teva's marketing of its proposed products and an order prohibiting their FDA approval.

More specifically, P&G's '122 patent claims compounds and pharmaceutical compositions containing risedronate, as well as methods of treatment using risedronate.

See, e.g., claims 4, 16, and 23. Merck's '329, '932, and '443 patents, under which P&G is licensed, all likewise claim the use of risedronate for treatment of osteoporosis. Claims 5, 20, and 34 of the '329 patent are respectively directed to methods of inhibiting, treating, and preventing bone resorption in a mammal by administering the compound risedronate. The '932 patent contains twenty claims, each of which is specifically directed to the use of one compound – risedronate. Finally, the '443 patent contains 54 claims, approximately 50 of which are limited to pharmaceutical compositions containing risedronate or "kits" containing risedronate dosing forms. Thus, P&G's statements in its letter to the Court of February 22, 2005 (D.I. #12) that "the patents at issue in each suit are completely different in kind" and that "Merck's [patents] relate to dosing regimens for bisphosphonates in general" could hardly be more misleading. In fact, even a cursory examination of the patents shows that they relate to the same subject matter – indeed, if the Merck patents and the P&G patent were directed to unrelated subjects, they would not all be asserted against the same Teva drug product.

The presence, as here, of related technology in two cases is typically a ground for consolidating them. In *Western States Machine Company v. S.S. Hepworth Company*, 37 F. Supp. 377 (E.D.N.Y. 1941), plaintiff asserted infringement of four patents in two cases. All the relevant structures could, but not necessarily would appear in an infringing product. *Id.* at 378. The court granted a motion to consolidate, finding that the same technology was at issue and that the cases could be more effectively adjudicated if they were consolidated. Here the patents in issue are all directed to the same technology – risedronate and its use. The multiplicity of patents does not present unrelated issues and so is not an impediment to consolidation.

II. THE ADVANTAGES OF CONSOLIDATION OUTWEIGH ANY POSSIBLE DISADVANTAGES

The many advantages of consolidation here are readily apparent. Consolidation of the two actions will "avoid unnecessary costs or delay" because the burden on the parties and the court will be reduced by having a single consolidated trial. Fed. R. Civ. P. 42 (a). This is especially true in this situation, where "the questions to be decided in both suits are highly technical and closely intertwined." *Rohm & Haas Co.*, 525 F. Supp. at 1310. In such cases, this Court has stated "[t]here is little logic in forcing the Court to educate itself on the intricate factual details and complex legal issues common to both suits on two occasions, in preparation for two separate trials."

Consolidation will also encourage orderly pretrial discovery and conserve party resources, as the two cases will involve much of the same documentary evidence and exhibits. Burdens on witnesses would also be reduced because witnesses with factual knowledge of the ANDA and Teva's proposed formulation (to the extent such testimony may be relevant) would only have to testify once. Judicial resources would also be conserved through consolidation of the cases by reducing the number of hearings, conferences, and trials. The relative expense to all concerned would be sharply reduced.

Moreover, simultaneous disposition of these actions will not cause inconvenience, delay, or expense. Both cases are at exactly the same stage, and in both cases the parties have agreed to exactly the same schedule going forward. If the cases are consolidated, they can proceed together under that agreed schedule.

CONCLUSION

In sum, the consolidation of the two actions will avoid unnecessary costs and delay, prevent duplication of evidence, conserve judicial resources and promote the administration of justice. Accordingly, the present action should be consolidated with the *Merck* litigation into a single, coherent cause.

Respectfully submitted,

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Dated: March 8, 2005

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CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, hereby certify that on March 8, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on March 8, 2005, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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